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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,164	07/23/2003	Eddie Reed	2002(227497)	8006
7590	03/23/2009			EXAMINER
Ralph A. Loren Edwards Angell Palmer & Dodge P.O.Box 55874 Boston, MA 02205				HOEKSTRA, JEFFREY GERBEN
			ART UNIT	PAPER NUMBER
			3736	
				MAIL DATE                    DELIVERY MODE
				03/23/2009                    PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/625,164	REED ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 March 2009.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 27-32,34-38 and 40-43 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 27-32,34-38 and 40-43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 June 2008 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/09/2009 has been entered.

### ***Notice of Amendment***

2. In response to the amendment filed on 03/09/2009, amendment(s) to the specification, amended claim(s) 27, 28, 30, 34, 35, 37, 38, and 40, new claim(s) 42-43, and cancelled claim(s) 1-26, 33, and 39 is/are acknowledged. The current objections and rejections is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Drawings***

3. Initially, the Examiner notes in Applicant's remarks filed 03/09/2009 (see page 6), Applicant apparently intended to cancel Figures 1A and 1B. This is improper. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. The drawings must show every feature of the invention

specified in the claims. Therefore, the structural limitations of the claimed invention must be shown or the feature(s) canceled from the claim(s).

4. The Examiner notes the previous unacceptable and informal drawings at least appeared an attempt to facilitate understanding of the invention by illustrating the claimed invention.

5. It remains, the drawings were received on 06/13/2008. These drawings are --*not acceptable*--.

6. The Examiner notes the drawings received on 06/13/2008 appear similar to those received on 04/19/2006.

7. The drawings are objected to because they (a) appear to be informal photocopies of the invention which are not formal hand drawn illustrations of the claimed invention, (b) appear to be illegible and accompanied by dark and/or stray markings, and (c) they do not clearly illustrate at least the claimed limitations comprising *inter alia*: the collection element, the brush with bristles, and the inner tube, and/or the shield.

8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

9. The disclosure is objected to because of the following informalities: the cancellation of the description of the drawings is improper. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. The drawings must show every feature of the invention specified in the claims. Therefore, the structural limitations of the claimed invention must be shown or the feature(s) canceled from the claim(s). No new matter should be entered or may be introduced in the required drawing. Appropriate correction is required.

***Claim Objections***

10. Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. The positive recitation in claim 40 of "detecting the presence of HPV in the specimen" does not further limit the positive recitation in claim 43 of "detecting the presence of HPV in the specimen" and may render the claim indefinite.

11. Claim 42 is objected to because of the following informalities: the positive recitation in line 2 of "a vaginal specimen" should apparently read "the vaginal specimen" or the like. Appropriate correction is required.

12. Claim 43 is objected to because of the following informalities: the positive recitation in lines 2-3 of "a vaginal specimen" should apparently read "the vaginal specimen" or the like. Appropriate correction is required.

***Double Patenting***

13. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

14. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. Applicant is advised that should claims 42 and 34 be found allowable, claims 43, 40, and 41 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

#### ***Claim Rejections - 35 USC § 102***

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claims 27, 34-38, and 40-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Edens et al. (US 6,521,190 B1, hereinafter Edens).

18. Edens discloses a method for detecting human papilloma virus (HPV) in a collected vaginal specimen (column 1 line 5 - column 2 line 30, column 4 lines 28-51), said method comprising:

- obtaining the specimen (abstract, column 3 lines 7-17) that contains cervical cells and few endocervical cells (column 1 line 5 - column 2 line 30) with a device (100,300) (as best seen in Figure 2) comprising a collection element (200) (as best seen in Figure 2) comprising a retractable inner tube (220), and a brush (210)

attached to said inner tube (as best seen in Figure 2) with a longitudinal axis and comprises bristles (210) (column 3 lines 12-17) that are substantially perpendicular to the brush longitudinal axis (as best seen in Figure 2),

- wherein said device further comprises a shield comprising an outer tube (110) surrounding the collection element (as best seen in Figures 1A and 2),
- wherein the inner tube inherently has an inner tube longitudinal axis and the inner tube longitudinal axis runs parallel to the brush longitudinal axis (as best seen in Figure 2),
- wherein the inner tube element and the outer tube element are cylindrical in shape (as best seen in Figure 2),
- wherein an inner tube length and an outer tube length are roughly equal (as best seen in Figure 2)
- wherein the bristles comprise a flexible plastic material (column 4 lines 23-28) selected from a group consisting of: polyethylene, polyurethane, polyvinyl chloride, polysiloxanes, and nylon, and
- wherein the device does not use an absorbent material to collect the sample (column 1 line 5 - column 2 line 30, column 4 lines 52-63); and
- detecting the presence of HPV, including high risk HPV, in the specimen through assaying (column 1 line 5 - column 2 line 30, column 3 lines column 4 lines 28-51).

***Claim Rejections - 35 USC § 103***

19. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
20. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edens in view of Zavada et al (US 2003/0049828 A1, hereinafter Zavada).
21. Edens teaches the claimed invention, as set forth and cited above, except for expressly disclosing specimen testing including (a) extracting DNA and amplifying HPV nucleic acid to detect the presence of HPV and (b) contacting the specimen with a multiple polypeptides that bind to a HPV antibody or protein and subsequent detection of the bound antibody or protein in the specimen.
22. Zavada teaches specimen testing including (a) extracting DNA and amplifying HPV nucleic acid (paragraphs 33-34) to detect the presence of HPV and (b) contacting the specimen with a multiple polypeptides that bind to a HPV antibody (paragraph 35) or protein (paragraph 40) and subsequent detection of HPV (paragraph 17) in the specimen.
23. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the biological sample collecting and biological sample diagnostic testing are known in Edens and Zavada. The only difference is the combination of the biological sample collection and testing

into a single invention. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the biological sample collecting and biological sample diagnostic testing as taught by Edens with the biological sample diagnostic testing as taught by Zavada to achieve the predictable results of increasing the efficacy of a medical process to effectively and accurately diagnose HPV in a specimen by using well known diagnostic techniques.

### ***Response to Arguments***

24. Applicant's arguments with respect to claims 27-32, 34-38, and 40-43 have been considered but are moot in view of the new ground(s) of rejection, wherein the new ground(s) or rejection relies upon a new and/or different interpretation of previously applied prior art and/or relies upon additional limitations not previously and expressly considered in a patentability determination.

25. However in lieu of the previously applied prior art forming a basis for the new ground(s) of rejection set forth and cited above, Applicant's arguments filed 03/09/2009 have been fully considered but they are not persuasive.

26. Applicant argues the anticipatory rejection of the claims under Edens, specifically arguing Edens does not disclose, teach, and/or fairly suggest

- “the instant claims require the brush used for sample collection be attached to the retractable inner tube of the recited device”,
- nor that the inner tube and the brush are a "unitary structure".

27. The Examiner disagrees, maintains the new ground(s) of rejection as set forth and cited above, and in response notes the following:

28. In response to Applicant's argument that Edens does not disclose, teach, and/or fairly suggest that "the instant claims require the brush used for sample collection be attached to the retractable inner tube of the recited device". The Examiner as broadly as claimed Edens shows and discloses "a brush" (210) (column 3 lines 12-17) (as best seen in Figure 2) used for sample collection that is "attached" to "a retractable inner tube" (220) (column 3 lines 12-17) (as best seen in Figure 2).

29. Furthermore the Examiner notes absent any special definition in the specification upon which Applicant does not appear to be relying the claims and the terms comprising limitations therein are being treated on the merits with the broadest reasonable interpretation consistent with the plain meaning of the terms therein.

30. In response to Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the inner tube and the brush are a "unitary structure") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is

(571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey G Hoekstra/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736